UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ENDOTACH LLC,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 1:13-cv-01135-LJM-DKL
	)	
COOK MEDICAL INCORPORATED,	)	
	)	
Defendant.	)	

ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

After remand from the Court of Appeals for the Federal Circuit, the remaining issues in this case are directed to Plaintiff Endotach LLC's U.S. Patent No. 5,122,154 (the "'154 patent"). *See* Dkt. No. 271. This order addresses the relevant issues raised in Defendant Cook Medical Corporation's ("Cook's") Motion for Summary Judgment of Noninfringement, Invalidity and No Willfulness. Dkt. No. 146. The Court rules as follows.

I. SUMMARY JUDGMENT STANDARD

As stated by the Supreme Court, summary judgment is not a disfavored procedural shortcut, but rather is an integral part of the federal rules as a whole, which are designed to secure the just, speedy, and inexpensive determination of every action. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986); *see also United Ass'n of Black Landscapers v. City of Milwaukee*, 916 F.2d 1261, 1267–68 (7th Cir. 1990). Rule 56(a) provides in relevant part: "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."

Once a party has made a properly-supported motion for summary judgment, the

opposing party may not simply rest upon the pleadings but must instead submit evidentiary materials showing that a fact either is or cannot be genuinely disputed. Fed. R. Civ. P. 56(c)(1). A genuine issue of material fact exists whenever "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). The nonmoving party bears the burden of demonstrating that such a genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Goodman v. Nat'l Sec. Agency, Inc.*, 621 F.3d 651, 654 (7th Cir. 2010). It is not the duty of the Court to scour the record in search of evidence to defeat a motion for summary judgment; rather, the nonmoving party bears the responsibility of identifying applicable evidence. *See Goodman*, 621 F.3d at 654; *Bombard v. Fort Wayne Newspapers, Inc.*, 92 F.3d 560, 562 (7th Cir. 1996).

In evaluating a motion for summary judgment, the Court draws all reasonable inferences from undisputed facts in favor of the nonmoving party and views the disputed evidence in the light most favorable to the nonmoving party. *See Berry v. Peterman*, 60 F.3d 435, 438 (7th Cir. 2010); *Estate of Cole v. Fromm*, 94 F.3d 254, 257 (7th Cir. 1996). The mere existence of a factual dispute, by itself, is not sufficient to bar summary judgment. Only factual disputes that might affect the outcome of the suit in light of the substantive law will preclude summary judgment. *See Anderson*, 477 U.S. at 248; *JPM Inc. v. John Deere Indus. Equip. Co.*, 94 F.3d 270, 273 (7th Cir. 1996). Irrelevant or unnecessary facts do not deter summary judgment, even when in dispute. *See Clifton v. Schafer*, 969 F.2d 278, 281 (7th Cir. 1992). If the moving party does not have the ultimate burden of proof on a claim, it is sufficient for the moving party to direct the Court to the

lack of evidence as to an element of that claim. *See Green v. Whiteco Indus., Inc.*, 17 F.3d 199, 201 & n.3 (7th Cir. 1994). "If the nonmoving party fails to establish the existence of an element essential to [its] case, one on which [it] would bear the burden of proof at trial, summary judgment must be granted to the moving party." *Ortiz v. John O. Butler Co.*, 94 F.3d 1121, 1124 (7th Cir. 1996).

II. BACKGROUND FACTS[1]

A. THE '154 PATENT INVENTION STORY

The inventor, Dr. Valentine Rhodes ("Dr. Rhodes"), allegedly sketched early ideas of his invention on paper napkins and other scraps of paper, at least some of which he either threw away or otherwise destroyed shortly after drawing them. Dkt. No. 153-1, at 48; Dkt. No. 174 at 17. Brenda Rhodes ("Brenda"), Dr. Rhodes' wife, recalls that he had refined his idea regarding one device that "fit everything" and sketched a design on napkins in or around May 1989. Dkt. No. 174 at 17. Sonja Dungan ("Dungan"), Dr. Rhodes' "longtime secretary," recalls discussing a "Chinese finger cuff" idea with Dr. Rhodes in September or October 1989. Dkt. No. 174 at 17. Dungan further claims that on December 5, 1989, she witnessed and notarized Dr. Rhodes' "preliminary drawings," but she does not recall how long she reviewed the documents, and does not have a book in which she allegedly recorded the notarizations. Dkt. No. 153-1 at 50.

[1] The Court has attempted to set out the facts that are either undisputed or, if disputed, in the light most favorable to the non-moving party. Objections are ruled upon within this Order and any usable evidence is likewise set forth in the light most favorable to the non-moving party. If a party failed to support an objection with a citation to evidence in the record, the Court considered the evidence cited by the proffering party and set forth the facts supported by the evidence. In order to streamline this Order, unless otherwise noted the Court will cite to the ECF page number or numbers where the relevant facts are set forth in a party's brief and such citation should be presumed to include the exhibits cited therein.

In or around late March or late April 1990, Dr. Rhodes dictated a first draft of the '154 patent application via audiocassette tape and gave it to Dungan to transcribe. *Id.* On April 24, 1990, Dr. Rhodes had Ms. Dugan notarize a detailed set of drawings, and a draft patent application. Dkt. No. 174-19 at ¶¶ 40, 44.

Some early sketches might have been in Dr. Rhodes' belongings and given to Brenda for safe-keeping; however, Brenda cannot find them and admits that some of Dr. Rhodes' and her papers may have been thrown away when she moved in 2009. Dkt. No. 153-1 at 48.

William Cuffari ("Cuffari") claims that he was a close friend of Dr. Rhodes' and that Dr. Rhodes showed him the early sketches of his design on paper napkins or other scraps and that he documented these meetings with Dr. Rhodes. *Id.* at 48. Cuffari claims that he kept papers and correspondence about Dr. Rhodes and/or his work, but they were destroyed in a 2005 flood. *Id.* Cuffari does not recall the season, day, month he allegedly saw Dr. Rhodes' sketches, or when they might have been created; he only recalls seeing one alleged drawing in 1988. *Id.*

Barry Stein ("Stein") of Caesar Rivise, was Dr. Rhodes' patent counsel. *Id.* at 46. Stein has practiced at Caesar Rivise since 1972, and has been recognized as a "SuperLawyer" patent litigator since 2005. *Id.* Stein claims to be "one of the country's leading Intellectual Property lawyers" and "has spent his entire professional career enforcing and protecting his clients' patents . . . ." *Id.* at 46-47. Stein has prosecuted patent applications for medical devices for many decades, has long known of Cook, and understood Cook to be "a player" in the medical device industry. *Id.* at 49. Based on his experience, Stein has long been familiar with the cardiovascular industry and stent

developments. *Id.* USPTO records indicate that Stein prosecuted the Rhodes patents, but he "recall[s] little about these patent applications. It's over twenty years." *Id.* Stein also does not remember anything relevant about drawings he turned over in discovery. *Id.* at 49-50. However, Endotach is relying upon Stein's documents to tell the invention story. *Id.* at 50 (citing Dkt. No. 136 at 5-9).

Dr. Rhodes died in December 2000. Dkt. No. 144 at 9.

B. THE PATENT IN SUIT

The application that matured into the '154 patent was filed on August 15, 1990. Dkt. No. 153-1, at 12; Dkt. No. 144 at 5. The '154 patent is directed to an intraluminal and endovascular graft for placement within a blood vessel, duct, or lumen to hold it open. Dkt. No. 148-1, '154 Patent, Abstract. The graft is composed of a flexible, tubular member or sleeve with multiple stents mounted on the periphery of the tube. *Id.* The '154 patent issued on June 16, 1992. *See id.* Date of Patent.

The asserted claims of the '154 patent read:

> 1. An intraluminal graft for introduction within a portion of a blood vessel, duct or lumen of a living being, said graft comprising a sleeve and at least two stent means mounted thereon, said sleeve being an elongated member of a generally tubular shape having a longitudinal axis and formed of a first, relatively flexible, material, said material being impervious to the ingrowth of tissue therein, each of said stent means being generally ring-like in shape, [s]aid stent means being mounted about the periphery of a surface of said sleeve at selected points therealong to form (a) respective first sleeve sections, each of said first sleeve sections extending for respective portions of the length of said sleeve and being spaced from each other, said sleeve additionally comprising at least one second section, said second section being interposed between said at least two first sections, each of said stent means being arranged to be expanded from a compact state to an expanded state as said sleeve is so expanded so that the cross-section area of the interior of said sleeve is enlarged, said stent means when in said expanded state being resistant to contraction back to said compact state to thereby hold said sleeve in said compact state to thereby hold said sleeve in said expanded state, said graft being able to bend longitudinally with

respect to said axis to enable said graft to be readily accommodated within a curved blood vessel, duct or lumen.

* * *

14. An intraluminal graft for introduction within a portion of a blood vessel, duct or lumen of a living being, said graft comprising a sleeve and stent means mounted thereon, said sleeve being an elongated member of a generally tubular shape having a longitudinal axis and formed of a first, relatively flexible, material, said material being impervious to the ingrowth of tissue therein, said sleeve comprising an outer peripheral surface, said stent means being generally ring-like in shape and mounted on said outer peripheral surface of said sleeve to form a first sleeve section, said stent means being arranged to be expanded from a compact state to an expanded state as said sleeve is so expanded so that the cross-sectional area of the interior of said sleeve is enlarged, said stent means when in said expanded state being resistant to contraction back to said compact state to thereby hold said sleeve in said expanded state, said graft being able to bend longitudinally with respect to said axis to enable said graft to be readily accommodated within a curved blood vessel, duct or lumen.

15. An intraluminal graft for introduction within a portion of a blood vessel, duct or lumen of a living being, said graft comprising a sleeve and stent means mounted thereon, said sleeve being an elongated member of a generally tubular shape having a longitudinal axis, an outer peripheral surface, and being formed of a first, relatively flexible, material, said material being impervious to the ingrowth of tissue therein, said stent means being generally ring-like in shape and mounted on said outer peripheral surface of said sleeve to form a first sleeve section, said first sleeve section extending for only a portion of the length of said sleeve to form a first sleeve section, said first sleeve section extending for only a portion of the length of said sleeve, said sleeve additionally comprising a second sleeve section contiguous with said first sleeve section, said stent means being arranged to be expanded from a compact state to an expanded state as said sleeve is so expanded so that the cross-sectional area of the interior of said sleeve is enlarged, said stent means when in said expanded state being resistant to contraction back to said compact state to thereby hold said sleeve in said expanded state, said first and second sleeve sections being able to bend longitudinally with respect to said axis to enable said graft to be readily accommodated within a curved blood vessel, duct or lumen.

Id. at 3-4 (citing ‘154 Patent, col.9, l.28 to col.10, l.67).

The parties had agreed on the meaning of two terms in the ‘154 patent, “first sleeve section[s]” and “second sleeve section[s].” Dkt. No. 102, Claim Construction Order, at 10

("CCO"). The parties disputed two additional claim terms and, on April 10, 2013, the Court issued its Order on the construction of those terms. *See*, *generally*, *id.* The following chart summarizes the terms and the Court's construction:

CLAIM CONSTRUCTION CHART FOR THE '154 PATENT	
DISPUTED TERM	**COURT'S CONSTRUCTION**
"stent means"	"a generally ring-like, hollow support that is resistant to contraction back to a compact state once it has been expanded"
"resistant to contraction back"	"able to withstand the force or effect of"

Notwithstanding the Court's discussion regarding construction for these terms, the parties dispute the scope of the "resistant to contraction back" element. Dkt. No. 153-1 at 26-27; Dkt. No. 174 at 24-26; Dkt. No. 196 at 9-11. In its CCO, the Court explained the scope of this term at length, particularly with respect to its limitation on the stent means:

> The plain meaning of the term stent, in combination with this material and/or mechanical requirement [(referring to the "resistant to contraction back" element)], limit the invention to that subset of stents that have the requisite structural properties. Whether those properties are obtained through the choice of material; or the design of the hollow, rink-like part; or a combination of the two, as disclosed in the description of the preferred embodiment; the invention does not preclude the use of a self-expanding stent.

CCO at 18. In further elaborating on the characteristics of "resistant to contraction back," the Court stated that "the stent must be able to withstand or hold off the force trying to close the sleeve once it has been expanded." *Id.* at 20. In other words, it must "hold the sleeve in its expanded state." *Id.* However, the Court rejected the notion that contraction back is precluded and refused Cook's invitation to import a limitation from the preferred embodiment into the claims. *Id.* at 21-22.

In addition to their arguments about the scope of the "resistant to contraction back"

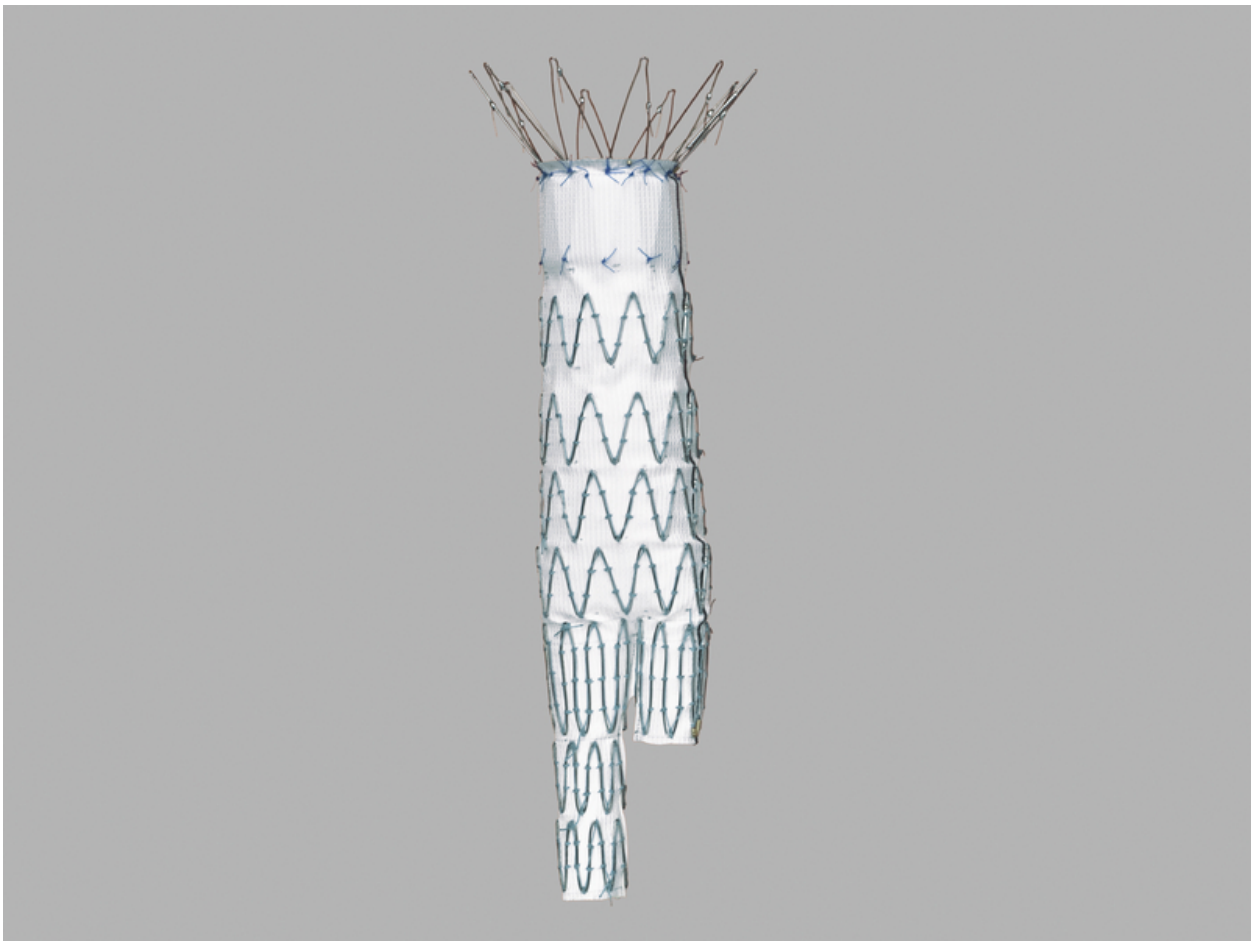
element, the parties dispute the meaning of an additional term "impervious to the ingrowth of tissue therein." Dkt. Nos. 153-1 at 25-26; Dkt. No. 174 at 20-24; Dkt. No. 196 at 8-9.

C. THE ACCUSED PRODUCTS

Endotach asserts that four of Cook's products infringe one or both of the Rhodes patents: (1) Zenith Flex AAA Endovascular Graft ("Zenith Flex"); (2) Zenith Renu AAA Ancillary Graft ("Zenith Renu"); (3) Zenith Fenestrated AAA Endovascular Graft ("Zenith Fenestrated"); and (4) Zenith TX2 TAA Endovascular Graft ("Zenith TX2") (collectively, the "Accused Products"). Dkt. No. 153-1 at 11; Dkt. No. 43 at ¶ 16. The Accused Products are stent grafts made from a combination of materials and one or more self-expanding stents. Dkt. No. 153-1 at 11.

In practice, a doctor places an accused product into a patient's aorta, the main blood vessel carrying blood away from the heart. *Id.* The aortic wall consists of three layers: the tunica intima (referred to as the intimal layer); the tunica media (referred to as the medial layer); and the tunica adventitia (referred to as the adventitial layer). *Id.* The intimal layer, which is the initial or intimal layer inside the vessel, is comprised of an endothelial cell layer, a subendothelial layer, and an internal elastic lamina layer. *Id.*; Dkt. No. 174 at 12-13.

The Accused Products have sleeves that are made from a woven Dacron® polyester fabric. Dkt. No. 153-1 at 16. The fabric is porous, which allows for tissue growth into the graft sleeve. *Id.* The Zenith Flex, for example, looks like this:



See Cook Medical, Inc., online Product Catalog, available at https://www.cookmedical.com/product/-/catalog/zenith-flex-aaa-endovascular-graft-bifurcated-main-body-graft?ds=ndo_aaamain_webds#, last visited June 7, 2017.

The alleged "stent means" in the Accused Products are called "Z-stents," which reflect their zig-zag configuration. Dkt. No. 153-1 at 16. Cook developed and patented them in the 1980s, years before the filing of dates of the Rhodes patents. *Id.* The stents may expand and contract slightly in response to forces in the body once the graft has been deployed. *Id.* at 16-17; Dkt. No. 174 at 14 & 25-26. Some of the Accused Products have fixation barbs. Dkt. No. 153-1 at 8; Dkt. No. 174 at 14. The fixation barbs provide "active fixation," meaning the barbs "will penetrate the aortic wall, to mimic the fixation

that you might get with a suture, for example, in a surgical procedure." *Id.*

D. ASSERTED PRIOR ART REGARDING THE '154 PATENT

1. Dr. Peter Lee's Stent Grafts & U.S. Patent No. 5,123,917

In 1989, Dr. Peter Lee ("Dr. Lee") disclosed, and later patented, designs for stent grafts. Dkt. No. 153-1 at 17. Specifically, Dr. Lee prepared a detailed invention disclosure (the "Lee paper") and had it notarized on May 16, 1989. *Id.* The Lee paper focuses on creation of a suitable surface for controlled healing of an atheromatous cavity to help combat restenosis. Dkt. No. 148-9 at 2. The Lee paper discusses a design for an "endothelial resurface device [that] is to be inserted percutaneously and placed via the vascular luminal side. (See Figure 1)." Dkt. No. 148-9 at 3. Figure 1 is reproduced below.

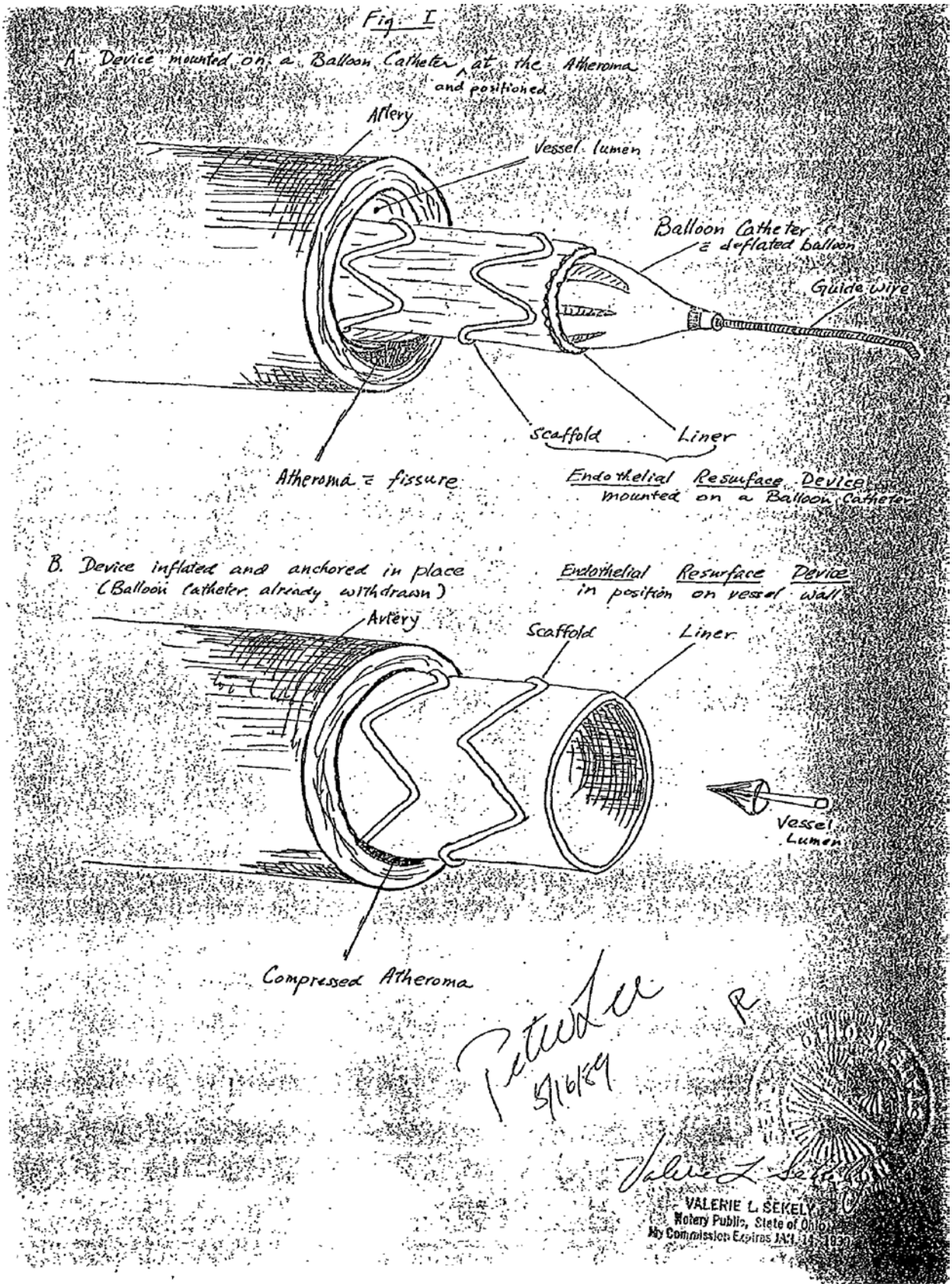


Fig. I
A. Device mounted on a Balloon Catheter at the Atheroma and positioned
Artery
Vessel lumen
Balloon Catheter
& deflated balloon
Guide Wire
Scaffold
Liner
Atheroma & fissure
Endothelial Resurface Device mounted on a Balloon Catheter
B. Device inflated and anchored in place (Balloon Catheter already withdrawn)
Endothelial Resurface Device in position on vessel wall
Artery
Scaffold
Liner
Vessel Lumen
Compressed Atheroma
5/16/89
VALERIE L. SEKELY
Notary Public, State of Ohio
My Commission Expires JAN. 14, 1990

Id. at 8. The Lee paper teaches:

> The endothelial liner is a composite and thin membranous structure that would act as a surface for endothelialization and as a barrier between the hematological elements and the injured vascular media. This membranous structure is mounted on a scaffolding structure that will serve both to anchor the endothelial liner to the vascular wall and to withstand the pressure of cellular growth that would tend to distort the luminal integrity.

Id. at 3. Lee contemplated that the endothelial liner would "consist[] of a luminal surface and a vascular surface that could be made up of two different materials of different physical and biological properties." *Id. See also id.* at 3-4 (citing Figure 2). With respect to the scaffold, the Lee paper suggests "surgical stainless steel in a corrugated ring structure . . . anchored into the liner, either in-between the two membranes in the manufacturing process or it can be attached to the liner after the lining material has been fabricated." *Id.* at 5. Spacing of the rings would depend upon "its position of anchoring on the lining material," but "no inter ring metal connection is necessary." *Id.* Figures 2 and 3 are reproduced below.

Fig II

A. Longitudinal and detailed diagram of the Device lining the artery.

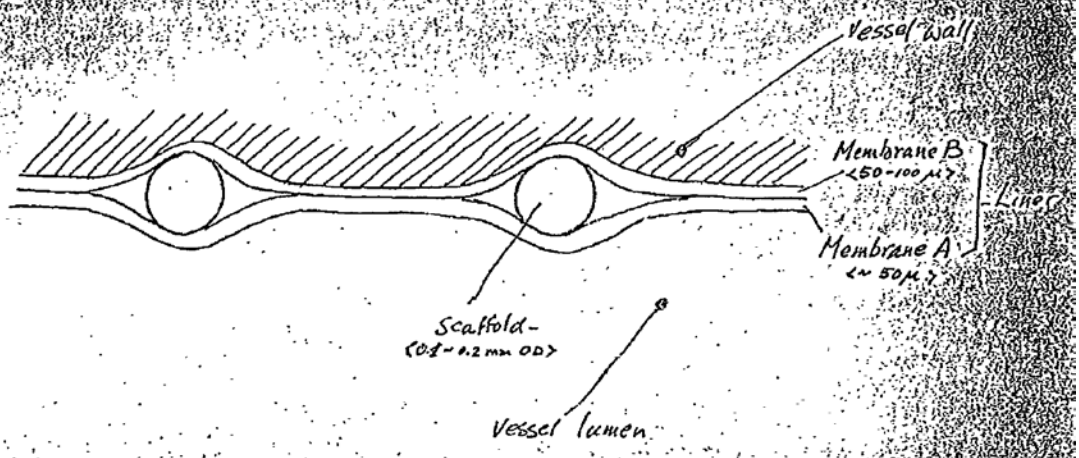


Diagram not to scale

B. Transverse section of the liner within the artery.

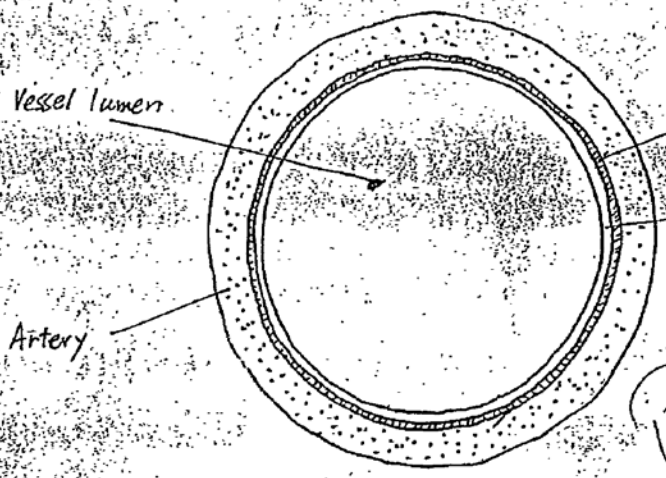
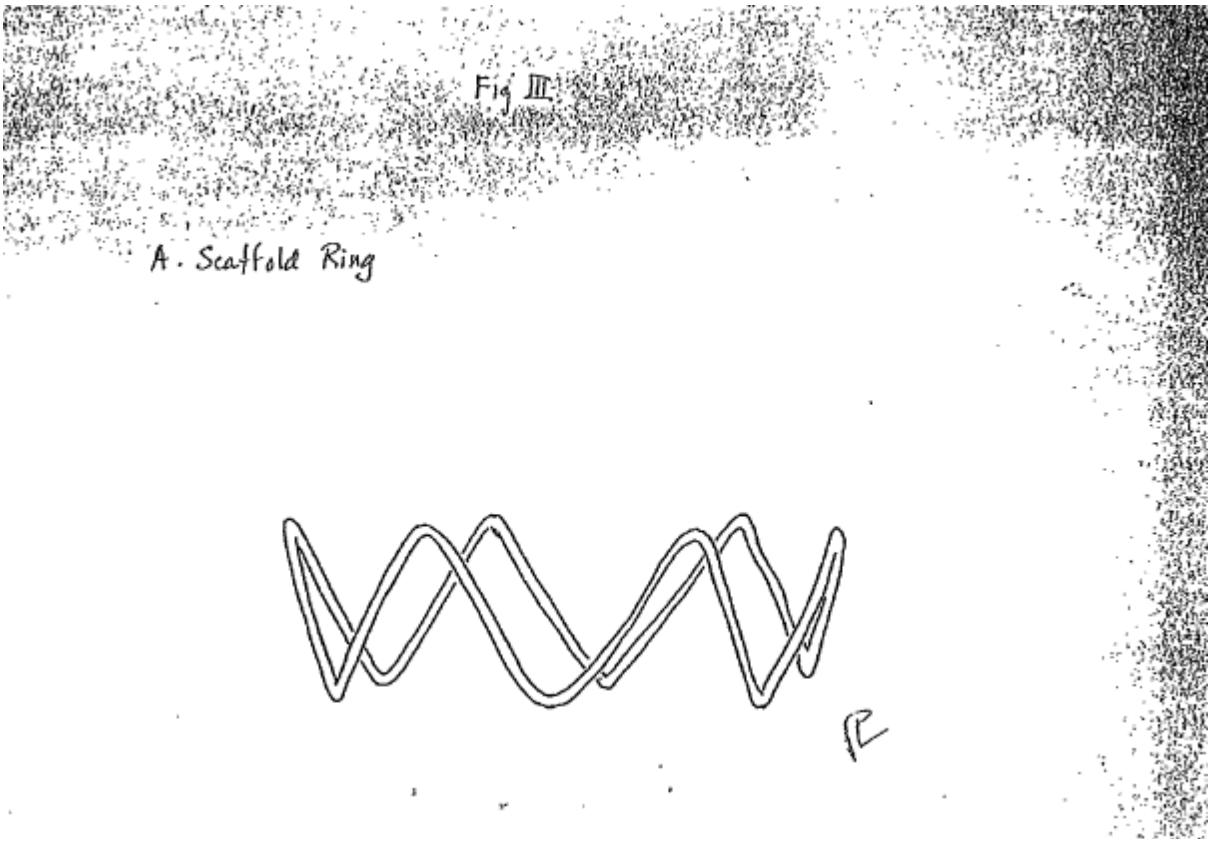


Diagram not to scale

5/16/89

VALERIE L SEKELY
Notary Public, State of Ohio
My Commission Expires Jan 14



Id. at 9-10.

On April 24, 1990, Dr. Lee signed a declaration endorsing his patent application directed to a stent graft. Dkt. No. 153-1 at 18-19. Three days later, on April 27, 1990, Dr. Lee filed the application that matured into U.S. Patent No. 5,123,917 (the "Lee patent"). *Id.* at 19. The Lee patent is directed to "[a]n expandable intraluminal vascular graft [that] includes a flexible cylindrical inner tube having a[n] outer periphery and plurality of separate scaffold member[s] mounted on the outer periphery of the inner tube. The scaffold members are expandable, ring-like and provide circumferential rigidity to the graft." Dkt. No. 148-12, Lee Patent, Abstract. Although the Lee patent expresses a preference for the spaced scaffold members to be sandwiched between inner and outer membranes, *id.* col.5, ll.11-15, it discloses and claims an alternative embodiment where there is a single membrane with inner and outer surfaces and where "it would be

advantageous to provide the rings on the outside in order not to have any barrier to blood flow through the graft." *Id.* at col.7, ll.21-49; *id.* at col.8, ll.54-57. This invention was disclosed in the specification of the application, and in one claim, in a modified form. Dkt. No. 148-11 at 14 (in the specification) & 17 (claim 7).

2. U.S. Patent No. 5,195,984 to Schatz

U.S. Patent No. 5,195,984 to Schatz (the "Schatz '984") issued on March 23, 1993, and claims priority to an application filed on October 4, 1988. Dkt. No. 153-1 at 19. The Schatz '984 is directed to

> [a] plurality of expandable and deformable intraluminal vascular grafts . . . [that] may be thin-walled tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members, and adjacent grafts are flexibly connected by a single connector member disposed substantially parallel to the longitudinal axis of the tubular member.

Dkt. No. 148-14, Schatz '984 Patent, Abstract. It discusses, among other things, the importance of the material characteristics of the tubular member, particularly that it must be expandable and deformable such that once it has been deployed, usually in its expanded state, the tubular member will "resist radial collapse." *Id.* col.5, ll.48-63. The patent notes that the tubular member "is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force. *Id.* col.7, ll.42-48; *id.* col.8, ll.59-68.

The "connector members" "flexibly connect adjacent tubular members **71** or grafts, or prostheses, **70**. Connector members **100** are preferably formed of the same material as grafts **70** . . . and . . . may be formed integrally between adjacent grafts **70**, or tubular members **71** . . . ." *Id.* at col.10, ll.28-36. Figure 8 of Schatz '984 illustrates the invention in practice:

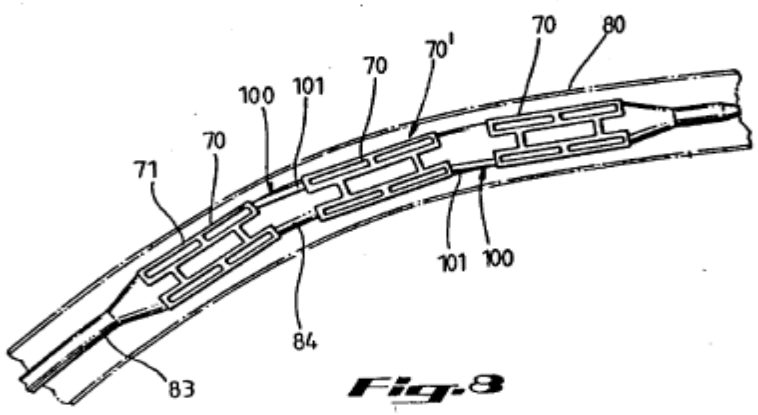


Fig.8

Id. at Sheet 3 of 3.

3. WO 89/08433 to Lazarus

World Intellectual Property Organization patent number WO 89/08433 to Lazarus ("Lazarus '433") published on September 21, 1989. Dkt. No. 153-1 at 19. Generally, Lazarus '433 is directed to an intraluminal graft that has a circular proximal staple and a circular distal staple, both of which have "wall-engaging members." Dkt. No. 148-15 at 2 & 6, Lazarus '433, Abstract & Summary of the Invention. Specifically, Lazarus '433 teaches:

> An artificial intraluminal prosthesis for placement in a fluid conducting corporeal lumen has a hollow graft of preselected cross-section and length. The proximal end of the graft is placed upstream with the lumen. The graft is deformable to conform substantially to the interior surface of the lumen. Staples are attached to the proximal end and preferably to the distal end of the graft for stapling the graft to the wall of the lumen.
>
> Each staple has wall engaging members. The wall engaging members of the proximal staple are generally angulated in a downstream direction and have tips for engaging the vessel wall. The wall engaging members of the distal staple are angulated in a direction generally perpendicular to the longitudinal or central axis of the graft, and also have tips for engaging the wall.

> Generally, the staples are formed into a v-shaped lattice or framework. In an alternative embodiment, the staples' framework is U-shaped or sinusoidal. The frame of the staples allows for radial deformation resulting in a spring-like effect when a compressed staple is allowed to expand within a vessel and to sustain itself in that expanded position.
>
> Preferably, the graft is made of a material suitable for permanent placement in the body such as nylon or Dacron. Prior to placement, the graft is formed to be substantially cylindrical in shape . . . .

Id. at 6, Lazarus '433, Summary of the Invention. Claim 24 of Lazarus '433 also states that the "intraluminal graft staple [is] positioned proximate the proximal end of said hollow graft for urging said hollow graft against he said interior surface and said vessel wall engaging members into said corporeal vessel." *Id.* at 28, Lazarus '433, Claim 24.

4. U.S. Patent No. 4,731,073 to Robinson

U.S. Patent No. 4,731,073 to Robinson ("Robinson '073") issued on March 15, 1988, and claims priority to an application filed on February 13, 1981. Dkt. No. 153-1 at 20 & n.7. Robinson '073 is directed to a multi-layered arterial graft prosthesis upon which or sandwiched within which a number of reinforcements can be employed. Dkt. No. 148-16 at 2, Robinson '073 Patent, Abstract. *See also id.* col.8, l.41 to col.9, l.4 (discussing spaced apart reinforcements of various configurations). Robinson '073 teaches that reinforcements that are spaced apart and not helical will not restrict the flexibility of the graft longitudinally, but will restrict it circumferentially. *Id.* col.8, ll.48-57; *id.* col.8, ll.60-64. Further, Robinson '073 suggests that the reinforcements need not be placed in the more complex, joined layers of the invention. *Id.* col.8, l.65 to col.9, l.4.

5. Nawa Article

In the January 1989 edition of the Journal of Thoracic and Cardiovascular Surgery, Sugato Nawa, M.D., and others published an article entitled, "Development of a New

Experimental Model for Total Exclusion of the Right Heart Without the Aid of Cardiopulmonary Bypass," ("Nawa 1989 article"). Dkt. No. 153-1 at 20 & n.8.

6. Schatz Article

In the February 1989 edition of the journal called Circulation, Richard A. Schatz, M.D., published an article entitled, "A View of Vascular Stents," ("Schatz article"). Dkt. No. 153-1 at 20 & n.9. The article traces the history of the development of vascular stents and describes the need for controlled thrombosis and minimization of abrupt closure and restenosis. Dkt. No. 148-25 at 2-7. The article teaches:

> A stent should be flexible enough to pass through narrow, tortuous passageways and yet, after expansion, still maintain a relatively stable, nonflexing, and nonshifting surface on which endothelial cells and neointima can grow most efficiently. One possible solution is shown in Figure 5. A modified Palmaz stent consisting of multiple short segments allows for "articulation" around bends of both guiding catheters and coronary arteries, but once expanded, it becomes a stable surface. It is, therefore, longitudinally flexible but radially noncompliant.

Id. at 7. The article also describes the importance of reliable expandability as well as a large expansion ratio "to allow for the smallest possible deliver catheter." *Id.* at 10.

III. COOK'S OBJECTIONS TO DR. JAMES H. SILVER REPORT

Cook asserts that several of Endotach's expert's reports should be stricken. Specifically, Cook contends that Dr. James H. Silver's ("Dr. Silver's") Second, Third and Fourth Infringement Reports, and his Second Invalidity Report, were disclosed after the relevant deadline; therefore, the Court should strike them pursuant to *In re Ready-Mixed Concrete Antitrust Litig.*, 261 F.R.D. 154, 159-60 (S.D. Ind. 2009). Dkt. No. 196 at 28-29. Further, Cook objects to all of Dr. Silver's reports on the grounds that they were not prepared by him as required by Federal Rule of Civil Procedure 26(a)(2)(B). *Id.* at 29-32.

Rather, Cook claims that Endotach's counsel prepared the reports and "Dr. Silver simply parroted [counsel's] version of the facts." *Id.* at 30.

Endotach argues that each of Dr. Silver's reports were timely prepared and served under the circumstances. Dkt. No. 202 at 1-3. Further, Dr. Silver's declaration, which contains opinions that are consistent with those in his reports, is submitted properly in accordance with Southern District of Indiana Local Rule 56.1(e).[2] *Id.* at 3-4. Moreover, Endotach contends that Dr. Silver's reports comply with Rule 26(a). *Id.* at 4 (citing *Hoskins v. Gunn Trucking*, No. 4:07-CV-72-WCL, 2009 WL 2970399 (N.D. Ind. Sept. 14, 2009)). Specifically, Dr. Silver testified that, while he relied upon counsel to prepare a draft of his reports because he has never provided expert testimony before, the opinions contained in the reports came from Dr. Silver in the first instance and he carefully reviewed and edited the drafts before they were finished. *Id.* at 4-8. Finally, Endotach asserts that Cook has not suffered any harm from any alleged infirmities in Dr. Silver's reports because Cook's expert had the opportunity to rebut each of them and Cook deposed Dr. Silver regarding each of his opinions as well as the preparation of his reports. *Id.* at 8.

The Court concludes that Cook has failed to show any prejudice either from the allegedly late disclosures of supplemental reports or preparation of the reports by counsel; therefore, Dr. Silver's reports will be considered in this Order. Rule 26(a)(2)(B)

[2] Cook argument, in part, is directed to Dr. Silver's opinions regarding invalidity of U.S. Patent No. 5,593,417 (the "'417 patent"). Dkt. Nos. 153-1 at & 174 at 23-24. However, the '417 patent is no longer at issue in this matter. Dkt. No. 269 (referencing the Federal Circuit's opinion in No. 15-1784, which affirmed the invalidation of the '417 patent). Therefore, arguments with respect to the '417 patent have not been considered in connection with Cook's objection to Dr. Silver's opinions or reports.

requires that when a party discloses a testifying expert, it must provide a written report prepared and signed by the expert. Fed. R. Civ. P. 26(a)(2)(B). The Advisory Committee Notes to the Rule contemplate that attorneys may help prepare reports, but it must "be written in a manner that reflects the testimony to be given by the witness . . . ." Fed. R. Civ. P. 26, Advisory Comm. Note, 1993 Amendment, Subdivision (a), Paragraph (2). The Rule also provides that the disclosure must be supplemented as required by Rule 26(e). Fed. R. Civ. P. 26(a)(2)(E). The failure of a party to provide information as required by Rule 26(a) or 26(e) results in exclusion of the evidence "unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Here, as evidenced by the timeline presented by both Cook in its reply brief and Endotach in its surreply brief, Dr. Silver's initial report was timely. Dkt. Nos. 196 at 28; 202 at 2. In his supplemental report, Dr. Silver rebuts arguments made for the first time by Cook's expert, whose report was served on Endotach at the same time as Dr. Silver's was served on Cook. Dkt. No. 202 at 2. In his rebuttal report, Dr. Silver relied, in part, on a Canadian report that he discovered and that, arguably, Cook should have disclosed, in his discussion regarding the '417 patent. *Id.* However, there is no evidence that his rebuttal report was untimely. *Id.* Further, after review of Cook's expert report, Dr. Silver believed he needed to concede certain positions he had taken regarding infringement, therefore, he revised Exhibit C to his opening report in a supplemental report; no new opinions were expressed therein. *Id.* at 3. Similarly, Dr. Silver's declaration, Dkt. No. 174-19, is consistent with his prior reports, except with respect to prior art regarding his invalidity analysis as to the '417 patent, which is no longer at issue. *Id.* at 3-4. In other words, the relevant opinions themselves did not

change; therefore, Cook had full and fair opportunity to depose Dr. Silver about his opinions at his deposition.

With respect to the authorship of the documents, likewise, Cook had a full and fair opportunity to depose Dr. Silver about preparation of the reports. *Id.* at 4-8. Cook's thorough recitation of Dr. Silver's testimony in this regard evidences that Cook has not been prejudiced by any alleged problems with authorship. Dkt. No. 196 at 29-32. Indeed, although Cook points to instances where Dr. Silver could have more carefully reviewed drafts of his reports, it is clear from reading the entirety of his testimony on the subject that the reports are a fair and thorough reflection of his opinions. *See* Dkt. Nos. 173-74 & 202-2.

For these reasons, Cook's objection to Dr. Silver's various opinions with respect to the '154 patent is **OVERRULED**.

IV. NONINFRINGEMENT

Cook asserts that its devices do not infringe the '154 patent because the sleeve is not made from a material that is "impervious to the ingrowth of tissue therein" as required by the asserted claims. The company argues that the term "impervious" has its ordinary dictionary meaning of "impermeable or impenetrable," and because Dacron, woven polyethylene terephthalate ("PET")), is porous, it will not prevent tissue from growing into the lumen of the graft. Dkt. No. 153-1 at 25. Cook further states that application of the doctrine of equivalents is improper as to this term because it would read the limitation out of the claims. *Id.* at 25-26. Endotach argues that the proper meaning of the term "impervious" in the context of the claims is "not affected or influenced by" because the concern addressed by the limitation is to prevent recurrence of stenosis or occlusion of

the graft. Dkt. No. 174 at 21. PET is used in conventional grafts, Endotach asserts, and prevents tissue growth into the lumen, which is all the limitation requires. *Id.* at 22-23.

Construction of claim terms is a matter for the Court. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-89 (1996). In doing so, the Court considers what one of ordinary skill in the art at the time of invention would have understood the term to mean. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). The appropriate starting point is the words of the asserted and unasserted claims. *See Phillips*, 415 F.3d at 1314. "Common words, unless the context suggests otherwise, should be interpreted according to their ordinary meaning." *Desper Prods., Inc. v. Qsound Labs., Inc.*, 157 F.3d 1325, 1336 (Fed. Cir. 1998) (citing *York Prods., Inc. v. Ctrl. Tractor Farm & Fam. Ctr.*, 99 F.3d 1568, 1572 (Fed. Cir. 1996)). *See also Phillips*, 415 F.3d at 1314 (citing *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001)). Further, when there are several common meanings for a term, "the patent disclosure serves to point away from the improper meanings and toward the proper meaning." *Renishaw PLC v. Marposs Societá per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). *Accord Phillips*, 415 F.3d at 1315-17 (discussing the role of the specification in claim construction). In fact, the correct claim construction is the one that "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Renishaw*, 158 F.3d at 1250. *See also Phillips*, 415 F.3d at 136. Although there is a fine line between reading a claim in light of the specification and reading a limitation from the specification into the claim, the Court must look cautiously to the specification for assistance in defining unclear terms. *See Phillips*, 415 F.3d at 1323-24. If the patentee uses a term in a different

manner from its ordinary meaning, he must clearly state the special definition in the specification; in this way, the specification becomes a dictionary. *See Phillips*, 415 F.3d at 1316.

With respect to the "impervious to the growth of tissue therein" limitation, both parties present plausible interpretations of the term "impervious," but read in light of the specification, the Court concludes that the term means "effectively impermeable." As stated in the previously-quoted phrase, in the claims, the inventor describes that the sleeve material prevents tissue growth into the lumen. '154 patent, col.9, ll28-35 (claim 1); col.10, ll26-30 (claim 14); col.11, ll2-6 (claim 16); col.11, ll50-54 (claim 22); col.12, ll16-20 (claim 25); col.12, ll58-63 (claim 28). Identical language is used in the abstract and in at least one description in the Summary of the Invention. *Id.* Abstract; col.4, ll18-19. Further, this element directly addresses one of the problems the inventor identified in the prior art endovascular stents, which were mesh-like, open or perforated structures, "and hence susceptible to scar tissue ingrowth." *Id.* col.2, ll65-67. However, the inventor specifically stated that the sleeve could be made from "conventional vascular graft[]" materials, such as polytetrafluoroethylene ("PTFE"), but not limited to that conventional fabric. *Id.* col.5, ll66-68 to col.6, ll1-4; col.7, ll37-39. Further, the patent suggests that some ingrowth might occur: "While there may be some ingrowth into the wall of the member **28**, such growth does not extend through the wall into the interior of the graft. Thus, the subject graft reduces the chance of recurrent stenosis or occlusion from fibrous response in the blood vessel." *Id.* col.8, ll57-61. Therefore, the construction of the term "impervious" must include prior art stent materials, such as PTFE or PET, that are woven; and include materials that allow some ingrowth of tissue. Therefore, the best construction

of the term "impervious" in the '154 patent incorporates a caveat to its plain meaning of impermeable. The Court concludes that this can be accomplished by incorporating the concept of "effectively" from Endotach's proposed construction to make the proper definition: effectively impermeable.

Endotach has presented evidence that Cook's endovascular graft material, PET, in effect stops or prohibits tissue from growing into the interior of the sleeve. *See* Dkt. Nos. 173-34; 173-6; 174-20 at ¶¶ 124-34; 174-19 at ¶¶ 5-10. This evidence is consistent with the prior art materials mentioned in the '154 patent specification; therefore, a reasonable jury could conclude that the Accused Products infringe this element of the asserted claims. Therefore, Cook's motion for summary judgment on this ground is **DENIED**.

Cook further argues that the stents of the Accused Products lack a "stent means . . . resistant to contraction back" as required by the asserted claims. Dkt. Nos. 153-1 at 26-27; 196 at 9-11. Specifically, Cook avers that its stents will not hold their shape and "continue to expand and contract within the vessel after deployment." Dkt. No. 153-1 at 26. The Accused Products further have zig-zag-shaped stents without effective control over the final expanded configuration, which were criticized in the '154 patent specification. *Id.*; Dkt. No. 196 at 9-10. Cook asserts that the doctrine of equivalents cannot apply to this term because it was modified during prosecution to obtain patentability. Dkt. No. 153-1 at 26-27; Dkt. No. 196 at 10-11.

In contrast, Endotach asserts that the Cook has misconstrued the Court's claim construction by reading out the ability of the stent to stay open and prevent collapse of the sleeve, which is all that is required. Dkt. No. 174 at 24-25. Endotach's expert opines

that the Accused Products have enough radial stiffness to resist compression back to a fully contracted state; therefore, they literally infringe. *Id.* at 25-26 (citing Dkt. Nos. 174-20 at ¶ 154; 174-22 at ¶¶ 3-6; 174-19 at ¶¶ 16-26). Finally, Endotach argues that the doctrine of equivalents does not limit the stent means limitation. *Id.* at 26.

The Court agrees with Endotach that Cook has improperly narrowed the claim language and the Court's claim construction. As discussed at length above, the Court construed the terms "stent means" and "resistant to contraction back." *See*, *generally* CCO. The Court specifically rejected Cook's invitation to import a limitation from the preferred embodiment into the claims, namely that no movement back is allowed. CCO at 21-22. To the contrary, the Court concluded that the entirety of the stent means limitation prevents collapse back to its original state, but does not preclude some movement. *Id.*

With respect to this construction, Endotach has evidenced that the Cook grafts have enough radial stiffness to prevent them from collapsing back into their original state, which is all the claims require. *See* Dkt. Nos. 174-20 at ¶ 154; 174-22 at ¶¶ 3-6; 174-19 at ¶¶ 16-26. A reasonable jury could conclude from this evidence that the Accused Products infringe this element of the asserted claims. For this reason, Cook's motion for summary judgment of noninfringement on this ground is **DENIED**.

V. INVALIDITY

Cook asserts that several prior art references invalidate the '154 patent pursuant to §§ 102(a), (e), and/or (g). Dkt. Nos. 153-1 at 27, 29-30; 196 at 11-17. Because a patent is presumed valid pursuant to 35 U.S.C. § 282, Cook must prove invalidity by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 95

(2011). The '154 patent was filed prior to March 16, 2013; therefore, the Leahy-Smith America Invents Act ("AIA") amendments to 35 U.S.C. § 102 do not apply, *see* Pub. L. No. 112-29, § 3(n)(1), 125 Stat 284, 293 (2011). For this reason, all references to § 102 in this Order are to the pre-AIA version.

Invalidity based on "'[a]nticipation requires that all of the claim elements and their limitations [be] shown in a single prior art reference.'" *Old Reliable Wholesale, Inc. v. Cornell Corp.*, 635 F.3d 539, 544 (Fed. Cir. 2011) (quoting *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009)). *See also Trebo Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1169 (Fed. Cir. 2014). The prior art may either expressly or inherently disclose a limitation. *See Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). Anticipation is a question of fact. *See Telemac Cellular Corp. v. Topp Telecomm'cn. Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001). However, summary judgment may be appropriate "if the record reveals no genuine issue of material fact." *Encyclopedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1349 (Fed. Cir. 2010).

The parties present argument regarding the extent to which both the Lee paper and the Lee patent are prior art under §§ 102(a), (e), or (g). *Compare* Dkt. Nos. 153-1 at 29-30; & 196 at 11-16 *with* Dkt. Nos. 174 at 33-35 & 37-38; & 202 at 8-9. Section 102 states, in pertinent part:

> A person shall be entitled to a patent unless-- . . .
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this . . . country . . . before the invention thereof by the applicant for patent, or . . .
>
> * * *

> (e) the invention was described in . . . a patent granted on an application filed by another filed in the United States before the invention by the applicant for the patent . . . or . . .
>
> * * *
>
> (g) . . . (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of the invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. §§ 102(a), (e) & (g) (2002). "Conception is the 'formation, in the mind of the inventor, of a definite and permanent idea of a complete and operative invention, as it is hereafter to be applied in practice.'" *Solvay S.A. v. Honeywell, Int'l, Inc.*, 622 F.3d 1367, 1376 (Fed. Cir. 2010) (quoting *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (further citation omitted)). Reduction to practice can be actual or constructive; the latter "occurs when a patent application on the claimed invention is filed." *Id.* (citing *Hybritech*, 802 F.2d at 1376; *Frazer v. Schlegel*, 498 F.3d 1283, 1288 (Fed. Cir. 2007); *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998)).

Cook contends that there is no question of material fact that Dr. Lee was both first to conceive of and reduce to practice the inventions in the asserted claims of the '154 patent. Specifically, Cook claims that Endotach has no corroborating evidence that Dr. Rhodes conceived of all of the elements of his claimed inventions before April 24, 1990, based on his sketches and draft patent application. Dkt. No. 196 at 12-13. Further, with respect to Dr. Lee, on April 24, 1990, he signed a declaration endorsing his '917 patent application, which evidences that Dr. Lee conceived the material disclosed in the application at least by that date. Dr. Lee's application was filed shortly thereafter, on April

27, 1990, which is a constructive reduction to practice and well before the '154 patent application was filed on August 15, 1990. *Id.* at 11-13. Moreover, Cook asserts that the Lee paper evidences that Dr. Lee conceived of the invention disclosed in the '154 patent by May 16, 1989. *Id.* at 14-16.

Endotach relies on Dr. Silver's opinion to argue that Dr. Rhodes was the first to conceive and was diligent through constructive reduction to practice; therefore, none of Dr. Lee's disclosures are prior art, Dkt. No. 174 at 33-35; or at very least, there is a material question of fact as to the priority of Dr. Lee's disclosures, Dkt. No. 202 at 8-9. Specifically, Dr. Silver opines that Dr. Rhodes conceived of the '154 patented invention as early as December 5, 1989, and was diligent through constructive reduction to practice on the filing date of August 10, 1990. Dkt. No. 174 at 33. Further, Endotach argues that there is no corroboration that Dr. Lee conceived of a single-membrane sleeve prior to filing the Lee patent application, in April 1990, which precludes any possibility that his patent is prior art because both his conception and reduction to practice dates are after Dr. Rhodes' conception date. *Id.* at 34.

To the extent that Cook relies upon § 102(a), summary judgment is DENIED because there is no evidence that either the Lee paper or the Lee patented invention were "known . . . by others in this country . . . before" Dr. Lee filed the application that led to his invention. Prior knowledge of Dr. Lee's invention that was kept confidential is not public use under § 102(a). *See Minnesota Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1306 (Fed. Cir. 2002); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

Turning to §§ 102(e) and 102(g), the Court must consider what is disclosed by the Lee patent, the Lee application, and the Lee paper. The parties do not dispute that both the Lee patent and the Lee application disclose each element of the asserted claims. Dkt. Nos. 153-1 at 18-19, SOF 34 (stating that the Lee patent anticipates each of the asserted claims); 174 at 33-35 (arguing only that Dr. Rhodes invented the single-sleeve embodiment first); 196 at 11-12 (stating that Endotach presents no facts to evidence that the Lee patent fails to disclose the asserted claims); & 202 at 8-9 (arguing only that there is a question of fact on whether Dr. Lee's disclosure evidences a single-sleeve embodiment). The Court agrees that there is no material question of fact that both the Lee patent and the Lee patent application disclose each element of the asserted claims based on Cook's expert's clear and convincing chart that delineates each element of the asserted claims and the corresponding disclosure in the Lee patent and the Lee patent application, respectively. *See* Dkt. Nos. 149-1, ¶¶ 95-96, 99 (opining that the Lee patent discloses each element of the Asserted Claims); 149-3 at 84-117 (chart comparing the Asserted Claim elements with the Lee patent); 149-4 at 21-53 (chart comparing the Asserted Claim elements with the Lee patent application).

Endotach argues, however, that Dr. Rhodes was the first inventor by virtue of both his December 5, 1989, preliminary drawing and his April 24, 1990, draft patent application. Dkt. No. 154 at 23 (citing, *inter alia*, Dkt. No. 174-19 at ¶¶ 38, 40, 42, 44). But, as Cook points out, Dr. Rhodes' draft patent application, dated April 24, 1990, does not help Endotach. Dr. Lee endorsed his patent application on April 24, 1990. Dkt. No. 148-10. Dr. Lee testified that he understood the content of the application when he endorsed it. Dkt. No. 148-8 at 33-37. Endotach provides no evidence to rebut this

endorsement. Therefore, Cook as evidenced by clear and convincing evidence that Dr. Lee conceived of the inventions contained in the Lee application at least by April 24, 1990. The Lee application was filed a mere three days later, on April 27, 1990, which establishes Dr. Lee's constructive reduction to practice. *Solvay S.A.*, 622 F.3d at 1376. To the extent that Endotach relies on Dr. Rhodes' April 24, 1990, draft application as his date of conception, under § 102(g), Dr. Lee's invention takes priority because he conceived of the invention in the '154 patent at least on the same date as Dr. Rhodes, but reduced it to practice first when he filed his application in April, nearly four months prior to Dr. Rhodes.

This leaves Endotach to challenge Cook's argument that there is no evidence that Dr. Rhodes conceived of the '154 patented inventions earlier than April 24, 1990; and that, even if there is such evidence, the Lee paper shows that Dr. Lee conceived of the inventions earlier than Dr. Rhodes. Endotach asserts both that Dr. Rhodes' December 5, 1989, preliminary drawings evidence earlier conception of the '154 patented invention; and that the Lee paper fails to evidence conception by Dr. Lee in May of 1989. Endotach loses this argument.

Endotach relies on Dr. Silver's opinions and the testimony of Cuffari, Brenda, and Dungan to support its claim that Dr. Rhodes conceived of the patented inventions first. Dkt. No. 174 at 34-35 (citing Dkt. No. 174-19 ¶¶ 32-40, 42-44). But, Dr. Silver's opinion regarding Dr. Rhodes' conception is far from definitive. Specifically, he states, "Dr. Rhodes created 'preliminary drawings' on December 5, 1989, which demonstrate several of the elements of the invention claimed in the '154 Patent." Dkt. No. 174-19 ¶ 38 (citing Dkt. No. 153-11 (Rhodes preliminary drawings)). Dr. Silver further describes the origin of

those drawings as testified to by Dugan. *Id.* Nowhere in Dr. Silver's report or supporting materials, however, does he describe which "several . . . elements" are contained in the drawings and which are not. *See* Dkt. No. 174-19 ¶¶ 32-40, 42-44. Further, he cites to deposition testimony of Brenda, Dugan and Cuffari at length, *see id.*; but none of that testimony specifically describes all of the elements of the Asserted Claims either. Moreover, Dr. Silver fails to pull all the evidence together in a way that a reasonable jury could conclude that Dr. Rhodes had conceived of the inventions in the asserted claims by at least December 5, 1989. For this reason, there is no evidence that Dr. Rhodes conceived of the '154 patented invention earlier than Dr. Lee's patent application. Therefore, the '154 patent is invalid pursuant to § 102(e) and (g), and summary judgment in favor of Cook on this ground is **GRANTED**.

VI. CONCLUSION

The Court has concluded that Defendant Cook Medical is entitled to summary judgment on its defense that Plaintiff Endotach LLC's U.S. Patent No. 5,122,154 is invalid because it is anticipated. Defendant Cook Medical's Motion for Summary Judgment is **GRANTED in part and DENIED in part**. The Court will issue judgment accordingly.

IT IS SO ORDERED this 5th day of September, 2017.

LARRY J. McKINNEY, JUDGE
United States District Court
Southern District of Indiana

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